

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 27-44, 48-50, 52 are under consideration. Claim 27 has been amended to recite that the recited polysaccharides have an average molecular weight higher than 50 kD. New claim 52 has been added. Support for the change to claim 27 and new claim 52 may be found on page 3, lines 1-5 of the specification.

In the outstanding Official Action, claims 27, 35, 36, 39 and 44 were rejected under 35 USC §102(b) as allegedly being anticipated by WANG. This rejection is traversed.

*Aloe vera* is known to possess healing or curative characteristics. As a result, *Aloe vera* has been extensively studied in an effort to determine what portions of the *Aloe vera* are responsible for these properties. While it has been found that *Aloe vera* mainly contains water and polysaccharides, it is still somewhat speculative as to what polysaccharides in *Aloe vera* that account are responsible for these properties.

It has been found that not only do the monosaccharide units that make up the polymer chain of a polysaccharide, but also other factors such as the sequence order of linkages between the individual monosaccharides, as well as the anomeric configuration of linkages, may be responsible for the healing and curative properties of *Aloe Vera*.

The inventors have recognized for the first time that a composition exhibits remarkable healing properties when isolated polysaccharides derivable from Aloe vera, wherein a) the polysaccharides comprise 60-100% D-mannose, 40 - 0 % D-glucose and 0 - 10 % other monosaccharides b) the polysaccharides are negatively charged c) the polysaccharides bind to a positively charged column; and d) the polysaccharides have an average molecular weight higher than 50 kD.

In particular, hydrolyzation experiments have shown that the monosaccharide units in the negatively charged polysaccharides in this fraction contain mainly mannose. However, glucose and a small amount of other monosaccharides are also found.

WANG et al fail to disclose or suggest such a composition. The article by WANG et al. describes three polysaccharide fragments A60, A90a and A90b, wherein each fraction was isolated from Aloe vera leaves and purified on a Sepharose 6B-CL column. Although fragments A60 and A90b comprise mannose, there is no indication nor any suggestion in the article by WANG et al. that the fragments comprise polysaccharides that are negatively charged and bind to a positively charged column. Furthermore, the article by WANG et al. does not disclose or suggest polysaccharides with a molecular weight of at least 50 kD. In fact, the polysaccharide fragments have a molecular weight of 12 kD, 47 kD and 12 kD respectively.

Indeed, there is no indication that WANG obtains the same fraction as that recited in the claims. As a result, it can not be said that WANG would necessarily naturally or inherently anticipate the claimed invention. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

Therefore, it is believed that WANG fails to disclose or suggest the claimed invention.

The Examiner's attention is also respectfully directed to new claim 53, which recites a particular ratio for the mannose and glucose along with a particular range for the molecular weight of the polysaccharides (i.e., 100-300). It is believed

that claim 52 is even further distinguishable from WANG on this basis.

Claims 27-30, 35-37, 39, 42-44, and 49 were rejected under 35 USC §103(a) as allegedly being unpatentable over FARKAS et al. (3,360,511). Claims 27-30, 35-37, 39, 41, 42-44 and 48-50 were rejected under 35 USC §103(a) as allegedly being unpatentable over GAYST et al. (4,315,918). Claims 27-30, 35-37, 39, 41-44 and 48-50 were rejected under 35 USC §103(a) as allegedly being unpatentable over JIA (2002/0071868A1). Claims 27-30, 35-37, 39, 41, 42-44, and 48-50 were rejected under 35 USC §103(a) as allegedly being unpatentable over FARKAS et al. (3,360,511) in view of SHUPE et al. (6,290,964). These rejections are respectfully traversed.

FARKAS (US 3,360,511) is concerned with Aloe polysaccharides. The polysaccharides comprise about equal parts (35-40%) of glucose and mannose together with a small amount of glucuronic acid (1-2%). US 3,360,511 does not disclose negatively charged polysaccharides that bind to a positively charged column.

Applicants respectfully disagree with the Official Action that a person of ordinary skill in the art would reach the composition according to the invention by routine optimization. As the examiner is aware, a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the

determination of the parameter or variable might be characterized as routine or obvious. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). However, no such suggestion is provided by WANG.

Moreover, the present invention is concerned with a composition comprising polysaccharides. Routinely optimizing the amount of monosaccharides in a composition by adding these monosaccharides to the composition would, at best, result in a composition comprising a mix of the monosaccharides and not a polysaccharide.

Thus, even if the skilled person would synthetically make a polysaccharide out of monosaccharides, that skilled person would not find a suggestion or hint how to make the specific negatively charged polysaccharides which are derivable from *Aloe vera*, bind to a positively charged column and have a molecular weight of at least 50 kD according to the invention.

Indeed, in this regard, none of the other references that have been cited disclose or suggest the claimed polysaccharides. FAYST discloses that the gellation of polysaccharide gums such as guar or locust bean gum are inhibited by gelatin hydrolysates, at alkaline pH. Formulations of gum, gelatin hydrolysate and alkaliniser are reconstituted by shaking with water, and are easily imbibed. The inhibition is reversed by pH change in the

stomach allowing gellation to occur. The formulation is useful in treatment of hypercholesteremia, gastric disorders and as an adjunct to insulin therapy.

JIA relates to a vehicle for the delivery of biologically active agents. The vehicle, Maxcell, is formulated from a combination of natural plant extracts and is comprised of Aloe vera polysaccharide fraction Immuno-10 (i.e. a very particular type of fraction), cAMP, piperine, calcium phosphate and glycyrrhizinic acid.

SHUPE discloses antimicrobial agents and method for isolation of these agents from a gel liquid of Aloe vera, including at least one antimicrobial agent from the clear gel isolated from the whole leaf of the Aloe vera plant, wherein the antimicrobial agent is an agent produced by the Aloe vera and/or indigenous bacteria that colonize the Aloe vera plant, is disclosed. Thus, it is not even clear that components from the Aloe plant itself are required.

Moreover, none of them discloses polysaccharides with an amount of D-mannose of at least 60% and an amount of D-glucose of at most 40% that are negatively charged and bind to a positively charged column.

Thus, none of the cited documents, either taken alone or in combination, suggest to one skilled in the art to isolate specifically the negatively charged polysaccharides which are

derivable from Aloe vera, that bind to a positive column and have a molecular weight of at least 50 kD, and wherein the polysaccharides comprise 60-100% D-mannose, 0-40% D-glucose and 0-10% other monosaccharides.

The subsequent claims, being dependent on claim 27, are, as a consequence, also deemed to be both novel and non-obvious over the cited prior art.

Once again, the Examiner's attention is respectfully directed to new claim 53, which recites a particular ratio for the mannose and glucose along with a particular range for the molecular weight of the polysaccharides (i.e., 100-300). It is believed that claim 52 is even further distinguishable from the above-identified publications on this basis.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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